CLAIMS

1. A powdered formulation which is a freeze-dried mixture of a sensitive active material and an excipient containing:

from 0.01 preferably from 0.1, more preferably from 0.5 to 50 % by wt of the sensitive active material,

from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of the excipient,

wherein at least 0.1 % by wt of the mixture is an amorphous state.

2. A formulation according to claim 1, in which from 0.1, preferably from 0.5, more preferably from 1 to 50 % by wt of the freeze-dried mixture is in an amorphous state.

3. A formulation according to claim 1, containing:

from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in amorphous state,

from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of excipient in crystalline state,

0 - 5 % by wt of excipient in amorphous state.

4. A formulation according to claim 1, containing:

from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in crystalline state,

from 50 to 99.89, preferably to 99.8, more preferably to 99.4 % by wt of excipient in crystalline state,

0.1 - 5 % by wt of excipient in amorphous state.

5. A formulation according to claim 1, containing

from 0.01, preferably from 0.1, more preferably from 0.5 to 25 % by wt of amorphous or crystalline state of sensitive active material,

from 75 to 99.49, preferably to 99.4, more preferably to 99 % by wt of crystalline state excipient,

0.5 - 5 % by wt of excipient in amorphous state

6. A formulation according to any of claims 1 to 5 in which a saccharide is used to provide an excipient in amorphous state.

7. A formulation according to any one of claims 1 to 5 in which a sugar alcohol is used to provide an excipient in crystalline state.

8. A formulation according to any one of the preceding claims which additionally contains from 0.1 to 10% by wt (preferably from 1 to 10% by wt) of additive/stabilizer.

9. A formulation as defined in claim 8 wherein the additive/stabilizer is an antioxidant, a free radical scavenger and/or a Maillard reaction suppresser.

10. A formulation according to any one of the preceding claims wherein the sensitive active material is a labile organic and/or inorganic molecule, a biopolymer, a polypeptide, protein, enzyme, hormone, vitamin, antibiotic, polysaccharide, lipid, killed or live whole live cell.

11. A formulation according to claim 10 wherein the sensitive active material is a virus (including phage), bacterium, fungus and/or eukaryote.

12. A formulation according to any one of the preceding claims substantially as hereinbefore described.

13. A formulation according to any one of the preceding claims for use in therapeutic treatment of a human or animal body.

14. A dosage form comprising a formulation according to any one of the preceding claims.

15. A dosage form according to claim 14 which is a container which comprises the formulation according to any one of claims 1 to 13 or an article which has been formed from the formulation according to any one of claims 1 to 13.

16. A dosage form according to claim 14 or claim 15 for use in therapeutic treatment of a human or animal body.

17. Use of a formulation according to any one of the claims 1 to 13 in the manufacture of a medicament for use in therapeutic treatment of a human or animal body.

18. Use of a dosage form according to any one of the claims 14 to 16 in the manufacture of a medicament for use in therapeutic treatment of a human or animal body.

19. A method of preparing a powdered formulation which comprises forming a mixed solution of sensitive active material and excipient(s) containing:

from 0.01 preferably from 0.1, more preferably from 0.5 to 50 % by wt of the sensitive active material,

from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of the excipient,

and freeze-drying the solution so that at least 0.1 % by wt of the freeze-dried blend is in an amorphous state.

20. A method according to claim 19 in which the active material freeze dries to a crystalline state and the mixed solution contains:
from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in amorphous state,
from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of excipient in crystalline state,
0.1 - 5 % by wt of excipient which freeze dries to an amorphous state.

21. A method according to claim 19 in which the active material freeze dries to an amorphous state and the mixed solution contains:
from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in crystalline state,
from 50 to 99.89, preferably to 99.8, more preferably to 99.4 % by wt of excipient in crystalline state,
0 - 5 % by wt of excipient which freeze dries to an amorphous state.

22. A method according to claim 19, in which the mixed solution contains:
from 0.01, preferably from 0.1, more preferably from 0.5 to 25 % by wt of amorphous or crystalline state of sensitive active material,
from 75 to 99.49, preferably to 99.4, more preferably to 99 % by wt of crystalline state excipient,
0.1 - 5 % by wt of excipient which freeze dries to an amorphous state.

23. A method according to any of claims 19 to 22 in which a sugar is used to provide an excipient in amorphous state.

24. A method according to any of claims 19 to 22 in which a sugar alcohol is used to provide an excipient in crystalline state.

25. A method of medical treatment which method comprises supplying to a human or animal patient a therapeutically effective amount of a formulation according to any one of claims 1 to 13 or a therapeutically effective amount of a dosage form according to any one of claims 14 to 16.